DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 23, 2005

Damon P. Jones
Mc Guff Pharmaceuticals Inc.
2921 W. MacArthur Blvd.
Suite 141
Santa Ana, California 92704-6929

Dear Mr. Jones:

Your petition requesting the Food and Drug Administration to permit the filing of an Abbreviated New Drug Application (ANDA) suitability petition for Endrate (Edetate Disodium Injection, USP) in secondary package configurations of a single box containing one vial and/or trays containing twenty-five vials per tray, was received by this office on 02/23/2005. It was assigned docket number 2005P-0085/CP1 and it was filed on 02/23/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005P.0085

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